*Cofle*

P A T E N T

THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re U.S. Letters Patent of:)
Douglas M. Goumas) Application No.: 10/645,109
Patent No.: 6,953,441) Examiner: F. Dahbour
Issued: October 11, 2005) Art Unit: 3743

For: PREFORMED BRACE FOR TREATING METACARPAL FRACTURES AND METHOD
OF TREATING METACARPAL FRACTURES

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
**ATTENTION: Certificate
of Correction Branch**

CERTIFICATE OF MAILING	
I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail, postage prepaid, in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 ATTENTION: Certificate of Correction Branch on October 27, 2005	
By:	<u>Carol Prentice</u> CAROL PRENTICE

Certificate

NOV 04 2005

of Correction

Dear Sir:

Transmitted herewith is a Certificate of Correction for U.S. Patent No. 6,953,441 which issued October 11, 2005. Upon reviewing the patent, the patentee noted an error was made by the Patent and Trademark Office in printing the patent. Specifically, text was omitted from claim 22.

A Certificate of Correction is enclosed, and reads as follows:

(1) Column 7, line 53 should read:

--22. A method in accordance with claim 14, further comprising:--

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A copy of the Amendment dated January 31, 2005 is enclosed evidencing the requested correction. Claim 25 in the Amendment corresponds to the renumbered claim 22 in the patent.

Since the error for which a Certificate of Correction is sought was the result of Patent and Trademark Office mistake, no fee is due (35 U.S.C. §254). The issuance of the enclosed Certificate of Correction is therefore respectfully requested.

Attached hereto, in duplicate, is Form PTO-1050, with at least one copy being suitable for printing.

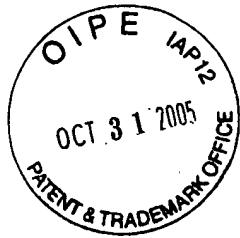
Please send the Certificate to Patentee's undersigned representative.

Respectfully submitted,



Douglas M. McAllister
Attorney for Applicant(s)
Registration No. 37,886
Lipsitz & McAllister, LLC
755 Main Street, Bldg. 8
Monroe, CT 06468
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ATTORNEY DOCKET NO.: DMG-101
Date: October 27, 2005



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
D. Goumas)
Serial No.: 10/645,109) Examiner: F. Dahbour
Filed: August 21, 2003) Art Unit: 3743
)
)

For: **PREFORMED BRACE FOR TREATING METACARPAL FRACTURES AND
METHOD OF TREATING METACARPAL FRACTURES**

MAIL STOP: AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first-class mail in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on: January 31, 2005.

Signature: Carol Prentice
Carol Prentice

AMENDMENT AFTER FINAL

Dear Sir:

This Amendment is responsive to the final Office Action mailed on January 19, 2005.
Please amend the above-identified U.S. patent application as follows:

Amendments to the Claims are reflected in the Listing of Claims which begins on page 2 of this paper.

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COPY**Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently amended) A preformed metacarpal fracture brace, comprising:

a one-piece semi-rigid molded outer shell contoured to conform to an outside portion of a wrist and hand of a wearer, said outer shell comprising a proximal section adapted to immobilize the wrist in an extension position and a distal section extending at an a fixed angle to the proximal section and adapted to immobilize at least the fourth and fifth metacarpals of the hand in a functional position at said angle;

a soft inner shell applied to an inside portion of said outer shell; and

a plurality of straps connected to said outer shell adapted to secure said brace onto said wearer; wherein:

said outer shell extends in a longitudinal direction from above the wearer's wrist to the tips of the wearer's fingers;

said proximal section of said outer shell extends in a direction transverse to the longitudinal direction at least from the outside portion of the wearer's wrist to approximately a midpoint of the wrist; and

said distal section of said outer shell extends in said transverse direction at least from the outside portion of the wearer's hand over said fourth metacarpal.

2. (Original) A brace in accordance with claim 1, wherein said outer shell has a C-shaped cross-section.

3. (Currently amended) A brace in accordance with claim 2, wherein said outer shell extends in a longitudinal direction from above the wearer's wrist to the tips of the wearer's fingers.

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4. (Original) A brace in accordance with claim 3, wherein:

 said proximal section of said outer shell extends in a direction transverse to the longitudinal direction at least from the outside portion of the wearer's wrist to approximately a midpoint of the wrist; and

 said distal section of said outer shell extends in said transverse direction at least from the outside portion of the wearer's hand over said fourth metacarpal.

5. (Original) A brace in accordance with claim 2, wherein said outer shell is open-ended along its width at a distal end and at a proximal end.

6. (Original) A brace in accordance with claim 1, wherein said angle comprises an angle in the range between 80 to 90 degrees.

7. (Currently amended) A brace in accordance with claim 1, wherein said outer shell is comprised of plastic which is malleable after heat-treating.

8. (Original) A brace in accordance with claim 1, wherein said straps comprise Velcro straps.

9. (Previously presented) A preformed metacarpal fracture brace, comprising:

 a one-piece semi-rigid molded outer shell contoured to conform to an outside portion of a wrist and hand of a wearer, said outer shell comprising a proximal section adapted to immobilize the wrist in an extension position and a distal section extending at an angle to the proximal section and adapted to immobilize at least the fourth and fifth metacarpals of the hand in a functional position at said angle;

 a soft inner shell applied to an inside portion of said outer shell; and

 a plurality of straps connected to said outer shell adapted to secure said brace onto said wearer;

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wherein said outer shell is conformed to the contours of the wearer's wrist and hand by heat-treating said outer shell after said brace is applied to said wearer.

10. (Currently amended) A brace in accordance with claim 1, A preformed metacarpal fracture brace, comprising:

a one-piece semi-rigid molded outer shell contoured to conform to an outside portion of a wrist and hand of a wearer, said outer shell comprising a proximal section adapted to immobilize the wrist in an extension position and a distal section extending at an angle to the proximal section and adapted to immobilize at least the fourth and fifth metacarpals of the hand in a functional position at said angle;

a soft inner shell applied to an inside portion of said outer shell; and
a plurality of straps connected to said outer shell adapted to secure said brace onto said wearer;

wherein said outer shell of said brace is adapted to be trimmed to conform to a wearer's hand and wrist.

11. (Currently amended) A brace in accordance with claim 10, wherein the proximal portion of the outer shell is adapted to be separated from the distal portion by cutting.

12. (Original) A brace in accordance with claim 1, wherein:

a first strap secures the brace above the wrist of the wearer;
a second strap secures the brace around a palm portion of the wearer's hand; and
a third strap secures the brace around fingers of the wearer.

13. (Currently amended) A brace in accordance with claim 1, wherein said outer shell is formed using a vacuum molding process.

14. (Currently amended) A method of treating metacarpal fractures, comprising:

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applying a preformed metacarpal brace to an injured hand and adjacent wrist, said metacarpal brace comprising:

a one-piece semi-rigid molded outer shell contoured to conform to an outside portion of the wrist and hand, said outer shell comprising a proximal section adapted to immobilize the wrist in an extension position and a distal section extending at an a-fixed angle to the proximal section and adapted to immobilize at least the fourth and fifth metacarpals of the hand in a functional position at said angle;

a soft inner shell applied to an inside portion of said outer shell; and

a plurality of straps connected to said outer shell adapted to secure said brace onto a wearer; and

trimming said outer shell of said brace to conform the brace to a wearer's hand and wrist;
and

tightening said brace around said wrist and hand using said straps in order to secure the brace to the wearer and to immobilize said wrist and said fourth and fifth metacarpals.

15. (Original) A method in accordance with claim 14, wherein said outer shell has a C-shaped cross-section.

16. (Original) A method in accordance with claim 15, wherein said outer shell extends in a longitudinal direction from above the wearer's wrist to the tips of the wearer's fingers.

17. (Currently amended) ~~A method in accordance with claim 16, A method of treating metacarpal fractures, comprising:~~

applying a preformed metacarpal brace to an injured hand and adjacent wrist, said metacarpal brace comprising:

a one-piece semi-rigid molded outer shell contoured to conform to an outside portion of the wrist and hand, said outer shell comprising a proximal section adapted to immobilize the wrist in an extension position and a distal section extending at an angle to

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the proximal section and adapted to immobilize at least the fourth and fifth metacarpals of the hand in a functional position at said angle:

a soft inner shell applied to an inside portion of said outer shell; and

a plurality of straps connected to said outer shell adapted to secure said brace onto a wearer; and

tightening said brace around said wrist and hand using said straps in order to secure the brace to the wearer and to immobilize said wrist and said fourth and fifth metacarpals;

wherein:

said outer shell extends in a longitudinal direction from above the wearer's wrist to the tips of the wearer's fingers;

said proximal section of said outer shell extends in a direction transverse to the longitudinal direction at least from the outside portion of the wearer's wrist to approximately a midpoint of the wrist; and

said distal section of said outer shell extends in said transverse direction at least from the outside portion of the wearer's hand over said fourth metacarpal.

18. (Original) A method in accordance with claim 15, wherein said outer shell is open-ended along its width at a distal end and at a proximal end.

19. (Original) A method in accordance with claim 14, wherein said angle comprises an angle in the range between 80 to 90 degrees.

20. (Previously presented) A method in accordance with claim 14, wherein said outer shell is comprised of plastic which is malleable after heat-treating.

21. (Original) A method in accordance with claim 14, wherein said straps comprise Velcro straps.

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22. (Previously presented) A method of treating metacarpal fractures, comprising:

applying a preformed metacarpal brace to an injured hand and adjacent wrist, said metacarpal brace comprising:

a one-piece semi-rigid molded outer shell contoured to conform to an outside portion of the wrist and hand, said outer shell comprising a proximal section adapted to immobilize the wrist in an extension position and a distal section extending at an angle to the proximal section and adapted to immobilize at least the fourth and fifth metacarpals of the hand in a functional position at said angle;

a soft inner shell applied to an inside portion of said outer shell; and

a plurality of straps connected to said outer shell adapted to secure said brace onto a wearer;

heat-treating said outer shell to conform the outer shell to the contours of the wearer's wrist and hand; and

tightening said brace around said wrist and hand using said straps in order to secure the brace to the wearer and to immobilize said wrist and said fourth and fifth metacarpals.

23. (Currently amended) A method in accordance with claim 14 ²², further comprising trimming said outer shell of said brace to conform the brace to a wearer's hand and wrist.

24. (Original) A method in accordance with claim 14, further comprising:

separating the proximal portion of the outer shell from the distal portion by cutting after a predetermined initial healing period; and

removing the proximal portion of the brace in order to allow wrist movement while maintaining immobilization of the fourth and fifth metacarpals.

25. (Original) A method in accordance with claim 14, further comprising:

tightening a first strap to secure the brace above the wrist of the wearer;

tightening a second strap to secure the brace around a palm portion of the wearer's hand;

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and

tightening a third strap to secure the brace around fingers of the wearer.

26. (Currently amended) A method in accordance with claim 14 22, wherein said outer shell is formed using a vacuum molding process.

27. (Original) A method in accordance with claim 14, wherein said brace is applied after a predetermined initial healing period during which the hand and wrist are immobilized using a cast.

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REMARKS

This Amendment is responsive to the final Office Action mailed on January 19, 2005. Claims 1, 3, 7, 10, 11, 13, 14, 17, and 26 are amended. Claims 1-27 are pending.

Claims 9 and 22 are allowed. The Examiner has indicated that claims 4, 10-11, 13, 17, 23-24, and 26 contain allowable subject matter.

Claims 1-8, 10-21, and 23-27 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description. In particular, the Examiner indicates that the term "fixed" added to claims 1 and 14 is not contained in specification. Claims 1 and 14 are amended herein to delete the term "fixed". Withdrawal of this rejection is therefore requested.

Claims 1-3, 5, 6, 8, 12, 14-16, 18, 19, 21, and 25 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Katzin (US 6,261,253).

Claims 7 and 20 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Katzin in view of Grim (US 5,058,576).

Claim 27 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Katzin

Applicant respectfully traverses these rejections in view of the amended claims and the following comments.

Discussion of Amended Claims

Claim 1 is amended to include the subject matter of claim 3 and the allowable subject matter of claim 4. Claim 1 is also amended to delete the term "fixed" objected to by the Examiner. Claim 3 is amended to depend from allowed claim 9. Claim 7 is amended to correct an error in the previous amendment.

Claim 10, which the Examiner indicated contains allowable subject matter, is amended into independent form by the inclusion of the subject matter of original claim 1. Claim 11 is amended to depend from claim 10. Claim 13 is amended to depend from allowed claim 9.

Claim 14 is amended to include the allowable subject matter of claim 23. Claim 23 is amended to depend from allowed claim 22.

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Claim 17, which the Examiner has indicated contains allowable subject matter, is amended into independent form by including the subject matter of original claims 14 and 16.

Claim 26 is amended to depend from allowed claim 22.

Accordingly, Applicant respectfully submits that all of the present claims are in condition for immediate allowance, as each of the claims either contains allowable subject matter as indicated by the Examiner, or depends from such a claim.

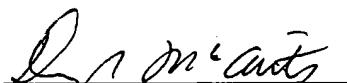
Further remarks regarding the asserted relationship between Applicant's claims and the prior art are not deemed necessary, in view of the foregoing discussion. Applicant's silence as to any of the Examiner's comments is not indicative of an acquiescence to the stated grounds of rejection.

Withdrawal of the rejections under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) is therefore respectfully requested.

Conclusion

The Examiner is respectfully requested to reconsider this application, allow each of the pending claims and to pass this application on to an early issue. If there are any remaining issues that need to be addressed in order to place this application into condition for allowance, the Examiner is requested to telephone Applicant's undersigned attorney.

Respectfully submitted,



Douglas M. McAllister
Attorney for Applicant(s)
Registration No.: 37,886
Lipsitz & McAllister, LLC
755 Main Street
Monroe, CT 06468
(203) 459-0200

Attorney Docket No.: DMG-101
Date: January 31, 2005

**UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION**PATENT NO. : 6,953,441 *B2*Page 1 of 1

APPLICATION NO.: 10/645,109

ISSUE DATE : October 11, 2005

INVENTOR(S) : Douglas M. Goumas

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 7, line 53 should read:

--22. A method in accordance with claim 14, further comprising:--

MAILING ADDRESS OF SENDER (Please do not use customer number below):

Lipsitz & McAllister, LLC
755 Main Street - Building 8
Monroe, CT 06468

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTIONPATENT NO. : 6,953,441 *B2*Page 1 of 1

APPLICATION NO.: 10/645,109

ISSUE DATE : October 11, 2005

INVENTOR(S) : Douglas M. Goumas

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